

K003330

JAN - 4 2001

**Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act**

July 1, 2000

1. General Provisions

Trade Name: Active Breathing Coordinator (ABC System)
Common Name: Patient Monitor

Applicant Name and Address: AKTINA Medical Physics
Corporation

360 North Route 9 W
Congers, New York, 10920
Phone: 914-268-0101
FAX: 914-268-1700
Registration Number: 2436865

2. Name of Predicate Devices

BCI International: Capnocheck II, K991086 1

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).

3. Classification

This device is classified as a class II device according to 21 CFR 892.5770.

4. Performance Standards

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product. EMC testing and UL certification were completed.

5. Intended Use and Device Description

The AKTINA Medical Physics Corporation ABC System is intended for use in Radiation Therapy as an aid in allowing the patient and treatment staff to visualize a patients breathing process and to maximize the time when a breath should be held to limit internal organ motion during treatment.

6. Biocompatibility

With the ABC System, the mouthpiece is in contact with the patient at any time when in use. Biocompatibility statements from the manufacturer of this component are included in this filing.

7. Summary of Substantial Equivalence

This device is similar in design and intended use and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Joan Zacharopoulos
Vice-President
Aktina Medical Physics Corp.
360 North Route 9W
Congers, NY 10920

Re: K003330
AKTINA Medical Physics Corporation
Active Breathing Coordinator (ABC System)
Dated: October 19, 2000
Received: October 24, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Zacharopoulos:

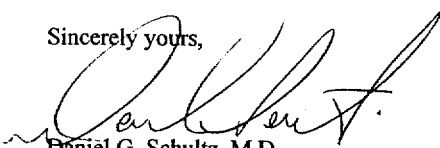
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number:

K003330

Device Name: Active Breathing Coordinator (ABC System)

Indications for Use:

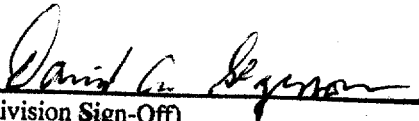
In radiation therapy, minimizing patient movement is essential for successful treatment, not only to minimize irradiating non involved tissue but to ensure complete irradiation of the target volume. A significant amount of internal patient movement is related to normal breathing (the processes of inhalation and exhalation). Patients are often asked to hold their breath for 15-30 seconds to minimize internal motion due to breathing. This is not always easily achieved for patients as they do not know the optimal time to begin a breath hold or whether it is easier for them to hold their breath upon inhaling or exhaling. The Active Breathing Coordinator provides a visual feedback system for the patient allowing them to see their breathing process and therefore better choose when to initiate a breath hold and therefore minimize internal organ motions during treatment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓

or

Over-The Counter Use: (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003330